



CERTIFICATE OF ANALYSIS

Nova Control Levels 1 and 2
Lot Number 23338021

Ref Number 18655
Exp Date 2025-11-15
Date of Manufacture 2023-11-15
UDI# (01)00385480186551(11)231115(17)251115(10)23338021

Level 1 L/N 23319026
Level 1 Exp Date 2025-11-15

	<u>Spec</u>	<u>Pass/Fail</u>
Na+ mmol/L	132 - 156	Pass
K+ mmol/L	3.2 - 4.0	Pass
Cl- mmol/L	95 - 114	Pass
TCO2 mmol/L	19 - 30	Pass
Glu mg/dL	69 - 91	Pass
BUN mg/dL	15 - 25	Pass
TCa mg/dL	5.04 - 7.24	Pass
Ca++ mg/dL	3.96 - 5.72	Pass
Mg++ mg/dL	0.98 - 1.74	Pass
Li+ mmol/L	0.56 - 0.87	Pass
pH	7.30 - 7.40	Pass

Level 2 L/N 23319027
Level 2 Exp Date 2025-11-15

	<u>Spec</u>	<u>Pass/Fail</u>
Na+ mmol/L	110 - 129	Pass
K+ mmol/L	5.6 - 6.8	Pass
Cl- mmol/L	76 - 92	Pass
TCO2 mmol/L	10 - 18	Pass
Glu mg/dL	233 - 309	Pass
BUN mg/dL	48 - 68	Pass
TCa mg/dL	7.74 - 10.91	Pass
Ca++ mg/dL	6.49 - 8.85	Pass
Mg++ mg/dL	3.38 - 4.65	Pass
Li+ mmol/L	1.84 - 2.56	Pass
pH	7.55 - 7.60	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer.

Awishi M

Approval

QC Inspector

Title

1/3/2024

Date